

# Vaccine Safety Working Group Update

NVAC Meeting  
June 2, 2010

Tawny Buck  
Co-Chair, Vaccine Safety Working Group

# Members

- Robert L. Beck
- Guthrie S. Birkhead\*
- Tawny Buck^
- Chris Carlson
- Vicky Debold
- Cornelia Dekker
- Mark Feinberg
- Steve Goodman
- Lance Gordon
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- James O. Mason
- Marie McCormick^
- Gerald Medoff
- Trish Parnell
- Andrew Pavia^
- William Raub
- L.J. Tan

\*Chair of NVAC

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# Charge 2

“To review the current federal vaccine safety system and develop a White Paper describing the infrastructure needs for a federal vaccine safety system to fully characterize the safety profile of vaccines in a timely manner, reduce adverse events whenever possible, and maintain and improve public confidence in vaccine safety.”

# VSWG Subgroups

## Content Subgroups

1. Structure/Governance
2. Epidemiology/Surveillance of Adverse Events
3. Biological Mechanisms of Adverse Events

## Process Subgroups

1. Stakeholder Engagement
2. Implementation

# Summary of Information Gathering

- July 15-16, 2009 Kick off meeting with 26 invited panelists
- Conference calls briefings with ~30 individuals involved in federal and non-federal vaccine safety activities

# Charge 2 Kick-Off Meeting

- July 15-16, 2009
- Invited 26 panelists to speak on:
  - Principles and policy alternatives for a robust vaccine safety system
  - Identifying innovative ways of overcoming gaps in vaccine safety science infrastructure
  - The ideal system to meet the needs of the public, public health, and healthcare professionals for confidence in vaccine safety
  - Lessons from other safety arenas
  - Enhancing the adoption and implementation of the NVAC white paper

# Briefings

- Barcoding technology
- CDC Immunization Safety Office
- CISA Biospecimen Repository
- CISA Investigators
- DoD Vaccine Healthcare Centers
- DoD Milvax Drug safety systems
- FDA/CBER
- International vaccine safety systems
- Manufacturers (VSWG members)
- NIH/NIAID
- Past IOM vaccine safety review committee consideration of biological mechanisms
- Post-Licensure Immunization Safety Monitoring (PRISM)
- VSD Investigators
- VA

# Summary of Progress to Date

## -Draft Documents-

- Definition of the goals for vaccine safety system
- Evaluation criteria for vaccine safety system, including functions and key attributes
- Identification of opportunities for improvement in the current vaccine safety system
- Options for structure and governance



# Proposed goals of the vaccine safety system

- Characterize the safety profile of vaccines and vaccination practice;
- Detect, prevent, and reduce adverse events in a timely manner;
- Develop guidance to detect and mitigate the effects of adverse events in individuals;
- Earn public confidence in the effectiveness of the vaccine safety system and in the safe use of vaccines; and
- Inform vaccine policy.

# Evaluation Criteria

## Functions

- Authority, Oversight, and Leadership
- Licensing
- Monitoring
- Research
- Causality Assessment
- Injury Compensation
- Practice
- Communications
- Engagement

## Attributes

- Accountability
- Effectiveness
- Efficiency
- Equity
- *Evidence-Based Decision Making*
- Initiative
- Innovativeness
- *Objectivity*
- Responsiveness
- *Transparency*

*Italics are those attributes highlighted as most important by SLC Writing Group*

# Public and Stakeholder Input

- Completed
  - Kick off meeting (July 15-16, 2010)
  - Salt Lake City meeting (April 11-13, 2010)
- Planned\*
  - Open Stakeholder meeting (Fall, 2010)
  - Solicit public and stakeholder written comments on draft report (Fall, 2010)
  - Other strategies under discussion

\*Subject to change

# Salt Lake City Meeting

- 29 additional federal and non-federal stakeholders, including 9 VSWG members
- Issues discussed
  - Opportunities for improvement in the current vaccine safety system
  - Proposed evaluation criteria
  - Strengths and weaknesses of various enhancements or alterations to the structure and governance of the vaccine safety system

# Major Topics of VSWG Discussion

- What are the research, infrastructure, and implementation needs for an improved vaccine safety system?
- Is there a place for internal and/or external assessment of federal vaccine safety activities?
- How can vaccine safety research be coordinated across all federal and non-federal partners, especially tying together basic science with clinical research and epidemiology?

# Next Steps

- Revise report based in June 1 discussions
- Apply evaluation criteria to alternate system configurations
- Implementation Subgroup visits with key decision makers
- Solicit feedback from stakeholders and the public
- NVAC vote at February NVAC meeting

# Acknowledgements

- July 15-16, 2009 Meeting participants
- April 11-13, 2010 SLC Writing Group participants
- The many individuals who took the time to brief the VSWG
- The Keystone Center